K013488 1/2

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10. SMDA Summary of Safety and Effectiveness SMDA Summary of Safety and Effectiveness

510(k) Summary
Sophy® SM8 Pressure Adjustable Valve System

A. Submittor Information

Sponsor:

SOPHYSA SA
C/o Interactive Consulting Inc.
70 Walnut Street
Wellesley, MA 02481
Tel: (781) 239-8108
Fax: (781) 863-6497

Manufacturer:

SOPHYSA SA
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69-41-3500

Contact Person: Jean-Christophe Audras, Regulatory Affairs

Date Prepared: October 15, 2001

B. Device Identification

Common/Usual Name:	Hydrocephalus Shunt
Proprietary Name:	Sophy® Pressure Adjustable Valve System, Model SM8
Regulatory Class:	Class II by 21 CFR 882.5550

C. Identification of Predicate Device(s)

The Sophy® SM8 is substantially equivalent to the SOPHYSA Sophy® SU8 (K992465) previously cleared and currently marketed.

D. Device Description

The Sophy® Pressure Adjustable Valve System SM8 is an implantable device designed for the treatment of hydrocephalus in adult and pediatric patients by shunting, thereby providing continuous, controlled intraventricular pressure and CSF drainage from the cerebral ventricles. Intraventricular pressure is maintained at a constant level by the device's ball-in-cone valve seat deign, and the value is pressure-adjustable transcutaneously. Drainage is directed to the abdominal cavity or to the right atrium of the heart. The Sophy® Pressure Adjustable Valve System SM8 technology allows for the non-invasive manual adjustment of the operating pressure via 8 pressure settings, ranging from 30 mm H_20 to 200 mm H_20, as follows: 30 = Low, 110 = Medium (intermediate 50, 70, 90) and 200 = High (intermediate 140, 170).

The principle of the Sophy® Pressure Adjustable Valve System SM8, nearly identical to that of its predicate Sophy®SU8 FDA cleared hydrocephalus valve (K992465), is based on the pressure change exerted on a synthetic ruby ball by a semi-circular spring at different points of its curvature. This spring is connected to a magnetic rotor whose position can be adjusted non-invasively by using a adjustment magnet oriented at different angles with selected orientations corresponding to different pressures. Radio-opaque identification dots indicate three main positions of the rotor corresponding to Low, Medium, and High operating pressures. For manual pressure setting, a specific adjustment kit is necessary, including a compass, magnet, and pressure selector.

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The Sophy® Pressure Adjustable Valve System SM8 is a miniaturized version of the predicate Sophy®SU8 (K992465), with a nearly 50% volume reduction and an approximately 45% weight reduction.

E. Substantial Equivalence

The Sophy® Pressure Adjustable Valve System SM8 is substantially equivalent to the Sophy® Pressure Adjustable Valve System SU8 (K992465) in terms of intended use, materials, design, performance, function, and operating characteristics.

F. Indications for Use

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

Sophysa SA
c/o Ms. Jacqueline E. Masse
Interactive Consulting, Inc.
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K013488
Trade Name: Sophy® Pressure Adjustable Valve System, Model SM8
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: January 22, 2002
Received: January 24, 2002

Dear Ms. Masse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013488

Device Name: Sophy® SM8 Pressure Adjustable Valve

Indications For Use:

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013488